



**UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/621,593 07/21/00 DE GROOT

N 4497US

HM12/0725

ALLEN C. TURNER  
TRASK, BRITT  
P. O. BOX 2550  
SALT LAKE CITY UT 84110

EXAMINER

WHITEMAN, B

ART UNIT

PAPER NUMBER

1633

DATE MAILED:

07/25/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

**Office Action Summary**

Application No.

09/621,593

Applicant(s)

DE GROOT ET AL.

Examiner

Brian Whiteman

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 and 17-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-14 and 17-22 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other:

### DETAILED ACTION

Claims 1-22 are pending and under consideration in the instant application.

#### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 10-13, 17-19, drawn to a transgenic non-human animal where in a cell of said animal comprises a recombinant nucleic acid encoding a protein capable of transporting an immunoglobulin from the cell's basolateral side to the cell's apical side; a method for collecting an immunoglobulin from a non-human animal comprising: providing a secretory cell of said animal, classifiable in class 800, subclass 13.
- II. Claims 1-9 and 21-22, drawn to an in vivo gene transfer method of transiently raising the concentration of a first class of immunoglobulins relative to at least a second class of immunoglobulin in a compartment of a body of a non-human animal or progeny thereof, classifiable in class 514, subclass 44.

Note: Group II will be examined to the extent that the invention encompasses a method of in vivo gene transfer.

Should applicant want group II to encompass transgenic non-human animals in group I, applicant should amend claims of group II to encompass a non-human animal whose genome comprises a protein capable of transporting an immunoglobulin from the cell's basolateral side to the cell's apical side. Then, group II will be rejoined with group I, so that the invention reads on transgenic non-human animals.

- III. Claim 20, drawn to a method of collecting an immunoglobulin from a non-human animal using a genus of unspecified material, classifiable in class 424, subclass 130.1.

The inventions are distinct, each from the other because:

Inventions I and II, III are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Invention I is directed to a transgenic non-human animal wherein a cell of said animal comprises a recombinant nucleic acid encoding a protein capable of transporting an immunoglobulin from the cell's basolateral side to the cell's apical side. Invention II is directed to an in vivo method of transiently enhancing expression of a first class of immunoglobulin relative to at least a second class of immunoglobulin in a non-human animal. Invention III is directed to a method for collecting an immunoglobulin from a non-human animal using an unspecified material. Invention I is not capable of use together with invention II and III, since invention I requires material for making a transgenic animal (e.g. embryonic stem cells). Therefore, Inventions I and II, and III are distinct inventions.

Because these inventions are distinct for the reason given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of inventions, and are separately classified and searched, restriction for examination purposes as indicated is proper.

It would be unduly burdensome for the examiner to search and consider patentability of all of the presently pending claims, a restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Tracey Johnson whose telephone number is (703) 305-2982.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on M-F, (730-400 EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark can be reached at (703) 305-4051.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 746-5024.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman

Application/Control Number: 09/621,503 <sup>593711/101</sup>  
Art Unit: 1633

Page 5

Patent Examiner, Group 1633  
July 18, 2001

*a*  
DAVE T. NGUYEN  
PRIMARY EXAMINER